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10/529,014	05/05/2005	Kengo Akimoto	47237-0532	8835

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,014	AKIMOTO ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 35* is/are pending in the application.

4a) Of the above claim(s) *20 - 31, 33 - 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 19, 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/24/05, 7/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I and a species of a triglyceride containing arachidonic acid (AA) as part or all of the constituent fatty acid in the reply filed on May 27, 2008 is acknowledged. The traversal is on the ground(s) that unity of invention was found during the examination of the parent PCT application and US Patent 6,080,787 and that the issue of serious burden is not addressed. Further, Applicant states that no species election can be required on a national stage application and that it is unclear to which group the species election applies.

This is not found persuasive because each case is treated on its own merits and the actions taken before the International Searching authority, other patent offices and/or other applications before the USPTO are not taken into account. The species election was indicated as being required if either group I or group II was elected, so it is unclear where Applicants point of misunderstanding regarding which group the species election belongs to is arising from. The cited section of the MPEP relates to applications which are before the International Searching Authority, which is not applicable as this application has entered the national stage. Applicant is referred to 37 CFR 1.449, Unity of Invention During the National Stage, which indicates that restriction in cases where lack of unity has been found is appropriate. Reasoning regarding lack of unity is put forth on p 4 of the Requirement for Restriction/Election.

It is noted that claim 35 was omitted from the Requirement for Restriction/Election mailed March 27, 2008. This claim should have been included in group I, the composition claims. However, in an amendment filed concurrently with the Response to the Restriction requirement, claims 1 – 19 and 29 – 32 of group I have been amended to recite a method of improving, enhancing or preventing decline of cognitive abilities of a healthy person, rather than compositions with intended use language. Claim 35 is therefore placed in a new restriction group IV, drawn to a composition containing arachidonic acid and/or a compound with arachidonic acid as a constituent fatty acid.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1 – 12 and 32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 12 and 31 of copending Application No. 10/485,456 in view of Wilatts et al. (Lancet 1998). The claims of the instant application recite a method of improving, enhancing or preventing decline of normal responses of cognitive abilities in a healthy person by administration of a composition comprising arachidonic acid and/or a compound with arachidonic acid as a constituent fatty acid.

The claims of '456 recite a method of treating or ameliorating a subject with symptoms or diseases caused by decreased brain function by administration of a

composition comprising arachidonic acid and/or a compound with arachidonic acid as a constituent fatty acid.

The claims of '456 do not recite administration of the composition to healthy people to improve the normal response of cognitive abilities.

Wilatts et al. discloses that administration of arachidonic acid to healthy, term infants results in improved three-step problem solving ability at 10 months of age (see summary, p 688).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to administer the composition of '456, claimed as being useful fro the treatment of subjects with decreased brain function, as Wilatts et al. discloses that administration of AA to healthy subjects results in increased normal responses of cognitive ability.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 – 19 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "normal responses of cognitive abilities of a healthy person" in claim 1 is a unclear and relative term which renders the

claim indefinite. The term "normal responses of cognitive abilities" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear whether these cognitive abilities are ones that all people share and abnormal cognitive abilities such as synesthesia, in which stimulation of one cognitive pathway leads to stimulation of a second cognitive pathway, are excluded. How these "normal" values of cognitive abilities all individuals share are determined is not provided (e.g., the average values for that ability for the person being treated, the average values for a person of the same chronological age, or the average values for an entire, non-age matched population) so what normal and abnormal are cannot be determined for these parameters which change over time, even in those individuals not suffering from any conditions or diseases other than aging. It is also unclear whether only the person need only be "healthy" in respect to their cognitive abilities and could be suffering from diseases or conditions that do not alter their cognitive abilities or if the person must be healthy in all respects and not suffering from any diseases or conditions or risk factors for a disease or condition. For example, would a person taking cholesterol lowering medication but not exhibiting high cholesterol be considered a healthy person?

6. Claims 1 – 19 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claims the subject matter which applicant regards as the invention. The method could be interpreted as improving

decline, enhancing decline, or preventing decline of normal response of cognitive abilities of a healthy person. Thus, the claims could be interpreted in a manner in which the outcome of the method are opposites – stopping the decline of cognitive abilities and accelerating the decline of cognitive abilities.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 13 – 19 and 32 rejected under 35 U.S.C. 102(b) as being anticipated by Willatts et al. (Lancet 1998).

Willatts et al. disclose a randomized trial of infant formula supplemented with long-chain polyunsaturated fatty acids (LCPUFA; p 688, col 2, last paragraph). The formula with LCPUFA contained 0.30 – 0.40 g of C20:4n-6 (another name for AA) per 100 g of fat and no eicosapentanoic acid (EPA, 20:5n-3; table 1, p 689). Therefore, the amount of EPA present is no more than 1/5 of the amount of AA present in the food composition. The persons given the infant formula were term infants (p 689, col 1, paragraph 1). Cognitive abilities were assessed at 10 months by completion of a problem solving task (p 689, col 1, paragraph 3). The results showed that the term infants three-step problem-solving ability is significantly improved by supplementation of

food formula with LCPUFA, including AA. The effects recited in claims 15 – 18 are inherently provided by the administration of AA and therefore while not appreciated by the cited prior art, the claim limitations are inherently met as a composition of the claimed ingredients is administered to persons not suffering from any medical conditions.

9. Claims 1, 2, 6, 8 and 13 – 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kiliaan et al. (US 2002/0040058).

Kiliaan et al. discloses method for the prevention and/or treatment of vascular disorders and/or secondary disorders associated therewith, such as depression, by the oral administration of a composition comprising long chain polyunsaturated fatty acids (paragraphs [0030] – [0031]). This fraction may contain free omega-3 and omega-6 fatty acids, but the fatty acids are preferably bound to a suitable backbone, for instance in the form of a triglyceride (paragraph [0036]). Preferred omega-6 LCPUFAs are AA and dihomogammalinolenic acid (paragraph [0038]). These patients being treated with this composition are suffering from disorders (anxiety, insomnia, seasonal effective disorder, etc.; paragraph [0077]) which do not effect their cognitive abilities and thus are persons who exhibit normal cognitive abilities, which are necessarily improved or the decline prevented by the administration of compositions comprising AA. The source of the triglyceride, as stated in claims 8, is a product-by-process limitation whose patentability is determined by the product, not the process used to obtain the product. There is no evidence to indicate that the triglycerides obtained from microbes belonging

to the genus *Mortierella* are different from the triglycerides in the used in the compositions of Kiliaan et al.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 2, 6 – 9, 13 – 19 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willatts et al. (Lancet 1998) in view of Barclay (US 5,583,019).

Willatts et al. discloses that supplementation of infant formula with LCPUFAs (p 688, col 2, last paragraph), including AA but not EPA (table 1, p 689), results in significantly improved three-step problem solving abilities in term infants at 10 months of age (p 689, col 1, paragraph 3).

Wilatts et al. does not disclose AA as a constituent moiety of a triglyceride.

Barclay discloses that arachidonic acid is an important precursor to many of the eicosanoids which regulate cellular metabolism and growth in infants (col 1, ln 28 – 30). The presence of other long chain highly unsaturated fatty acids such as EPA is undesirable as the other fatty acids can interfere with the utilization of AA and/or can inhibit blending of the AA-containing oil with other oils to achieve the appropriate ratio of fatty acids (col 1, ln 37 – 46). In example 5, the neutral oil fraction (containing triacylglycerides (triglycerides), col 15, ln 22 – 25) isolated from growths of *Mortierella* was found to contain 41 and 37% AA (table 8, col 15). The arachidonic acid is suitable for use as therapeutic and experimental agents (col 9, ln 9 – 10) in conjunction with a carrier for administration to infants (col 9, ln 13 – 25) or for the treatment of adults, in particular pregnant mothers (col 9, ln 32 – 34).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare an infant formula supplemented with AA in order to improve cognitive abilities of healthy infants, as taught by Willatts et al., and to use a triglyceride form of the LCPUFAs to provide the AA, as taught by Barclay. Additionally, the exclusion of large amounts of EPA from the composition would have been obvious given the teachings of Barclay that other LCPUFAs such as EPA can interfere with the beneficial effects of AA supplementation.

14. Claims 1 – 19 and 32 rejected under 35 U.S.C. 103(a) as being unpatentable over Wilatts et al. and Barclay as applied to claims 1, 2, 6 – 9, 13 – 19 and 32 above, and further in view of JP 08-214891 (1996, JP'891).

Wilatts et al. and Barclay teach a method of improving cognitive abilities in term infant by administration of a formula supplemented with AA, which can be in the form of triglycerides.

Wilatts et al. and Barclay do not disclose the position(s) at which the AA is attached to the triglyceride.

JP'891 discloses a method of making triglycerides that contain a high concentration of higher unsaturated fatty acids (LCPUFAs; paragraph [0001]). Positions 1 and 3 of the triglyceride are occupied by medium chain fatty acids, and the higher unsaturated fatty acid is at the 2 position, in a high concentration (paragraph [0009]). Examples of medium chains fatty acids contain 6 – 12 carbon atoms, such as caprylic (8 carbons) or capric acid (10 carbons; paragraph [0011]). With a docosahexanoic acid

at the 2 position, a reaction with an 8 carbon mideium chain fatty acids resulted in a concentration of the LCPUFA of about 30% (paragraph [0027]). The higher unsaturated fatty acid can be arachidonic acid, docosa-hexaenoic and/or eicosapentaenoic acid (paragraph [0011]). Preparation of these triglycerides allows for a higher concentration of the higher unsaturated fatty acids, which possess various bioactivities (paragraph [0037]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare an AA supplemented formula, with negligible amounts of EPA, to improve cognitive abilities as taught by Wilatts et al. and Barclay, and to prepare a triglyceride as taught by JP'891 in which the LCPUFA is present at the 2 position with medium chain fatty acids at the 1 and 3 positions, given the increased concentrations of the LCPUFA that can be obtained using such a preparation. The amount of triglyceride present in the composition in mole percent is not disclosed. However, amounts of LCPUFA which show effectiveness are presented. An artisan of ordinary skill in the art would determine the amount of AA that should be administered, and based on the amount of AA present in the prepared triglyceride, and optimize the amount of the triglyceride present in the composition to provide an effective amount of AA. The amount of AA in the composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ.

15. Claims 1, 13 – 19 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGahon et al. (Neurosceince 1997) in view of Willatts et al. (Lancet 1998).

McGahon et al. discloses that aging is associated with impaired performance in spatial learning tasks and impairment of the ability to sustain long-term potentiation (LTP) in the hippocampus (p 9, col 1, paragraph 1). A role for AA in the genesis of LTP has been suggested because AA enhances the synaptic response and inhibitors of AA metabolism inhibit LTP (p 9, col 2, paragraph 2). A decrease in AA utilization and concentration in the brain upon aging has been reported (p 10, col 1, paragraph 2). This change in membrane composition upon aging results in impairments in signal transduction mechanisms and transmitter functions (p 10, col 1, paragraph 2). Supplementation of the diet of aged (22 months) rats with AA resulted in sustained long-term potentiation and membrane levels of AA that was indistinguishable from that of 4-month-old control rats (abstract).

McGahon et al. does not disclose the treatment of humans with AA supplementation.

Wilatts et al. discloses that LCPUFA have important functional effects, some of which have been studied in rats (p 688, col 2, paragraph 1) but questions remain about the results in human infants (p 688, col 2, paragraph 2).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to apply the teachings of McGahon et al. as to the reversal of long term potentiation and membrane composition in aged rats by supplementation of AA

resulting in brain parameters comparable to 4-month old rats, and to apply the method to humans. Wilatts et al. discloses that rat models can have implications for human health. While shorter life spans and greater ease of conducting experiments makes rats a good candidate for such model studies, it would have been obvious to take the teaching gained in this model system and apply them to humans to determine if the effects of dietary supplementation in rats are also seen in humans, a more relevant treatment population than aged rats.

16. Claims 1 – 19 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGahon et al. and Wilatts et al. as applied to claims 1, 13 – 19 and 32 above, and further in view of JP 08-214891 (1996, JP'891).

McGahon et al. and Wilatts et al. disclose a method of reversing changes in brain function and composition that are associated with aging by supplementation of the diet with AA.

McGahon et al. and Wilatts et al. do not disclose the administration of AA as a constituent of a triglyceride, particularly one in which the AA is attached at the 2 position.

JP'891 discloses a method of making triglycerides that contain a high concentration of higher unsaturated fatty acids (LCPUFAs; paragraph [0001]). Positions 1 and 3 of the triglyceride are occupied by medium chain fatty acids, and the higher unsaturated fatty acid is at the 2 position, in a high concentration (paragraph [0009]). Examples of medium chains fatty acids contain 6 – 12 carbon atoms, such as caprylic

(8 carbons) or capric acid (10 carbons; paragraph [0011]). With a docosahexanoic acid at the 2 position, a reaction with an 8 carbon medium chain fatty acids resulted in a concentration of the LCPUFA of about 30% (paragraph [0027]). The higher unsaturated fatty acid can be arachidonic acid, docosa-hexaenoic and/or eicosapentaenoic acid (paragraph [0011]). Preparation of these triglycerides allows for a higher concentration of the higher unsaturated fatty acids, which possess various bioactivities (paragraph [0037]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare an AA supplemented formula, with negligible amounts of EPA, to improve cognitive abilities as taught by Wilatts et al. and Barclay, and to prepare a triglyceride as taught by JP'891 in which the LCPUFA is present at the 2 position with medium chain fatty acids at the 1 and 3 positions, given the increased concentrations of the LCPUFA that can be obtained using such a preparation. The amount of triglyceride present in the composition in mole percent is not disclosed. However, amounts of LCPUFA which show effectiveness are presented. An artisan of ordinary skill in the art would determine the amount of AA that should be administered, and based on the amount of AA present in the prepared triglyceride, and optimize the amount of the triglyceride present in the composition to provide an effective amount of AA. The amount of AA in the composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ.

17. Claims 1, 2, 6, 8, 9, and 13 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (US 2002/0040058) in view of Barclay (US 5,583,019).

Kiliaan et al. discloses method for the prevention and/or treatment of vascular disorders and/or secondary disorders associated therewith, such as depression, by the oral administration of a composition comprising long chain polyunsaturated fatty acids (paragraphs [0030] – [0031]). This fraction may contain free omega-3 and omega-6 fatty acids, but are preferably bound to a suitable backbone, for instance in the form of a triglyceride (paragraph [0036]). Preferred omega-6 LCPUFAs are AA and dihomogammalinolenic acid (paragraph [0038]). These patients being treated with this composition are suffering from disorders (anxiety, insomnia, seasonal effective disorder, etc. (paragraph [0077]) which do not effect their cognitive abilities and thus are persons who exhibit normal cognitive abilities, which are necessarily improved or the decline prevented by the administration of compositions comprising AA.

The compositions used in Kiliaan et al. contain an excess of EPA over AA.

Barclay discloses that arachidonic acid is an important precursor to many of the eicosanoids which regulate cellular metabolism and growth in infants (col 1, ln 28 – 30). The presence of other long chain highly unsaturated fatty acids such as EPA is undesirable as the other fatty acids can interfere with the utilization of AA and/or can inhibit blending of the AA-containing oil with other oils to achieve the appropriate ratio of fatty acids as found in breast milk (col 1, ln 37 – 46). In example, the neutral oil fraction (containing triacylglycerides (triglycerides), col 15, ln 22 – 25) isolated from a growth of

Mortierella strains was found to contain 41 and 37% AA (table 8, col 15). The arachidonic acid is suitable for use as therapeutic and experimental agents (col 9, ln 9 – 10) in conjunction with a carrier for administration to infants (col 9, ln 13 – 25) or for the treatment of adults, in particular pregnant mothers (col 9, ln 32 – 34).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composition as taught by Kiliaan et al. and to remove or at least significantly reduce the amount of EPA present, as the presence of EPA is taught by Barclay as interfering with the beneficial effects provided by AA.

18. Claims 1 – 9 and 10 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (US 2002/0040058) in view of JP'891.

Kiliaan et al. discloses method for the prevention and/or treatment of vascular disorders and/or secondary disorders associated therewith, such as depression, by the oral administration of a composition comprising long chain polyunsaturated fatty acids (paragraphs [0030] – [0031]). This fraction may contain free omega-3 and omega-6 fatty acids, but are preferably bound to a suitable backbone, for instance in the form of a triglyceride (paragraph [0036]). Preferred omega-6 LCPUFAs are AA and dihomogammalinolenic acid (paragraph [0038]). These patients being treated with this composition are suffering from disorders (anxiety, insomnia, seasonal effective disorder, etc. (paragraph [0077]) which do not effect their cognitive abilities and thus are persons who exhibit normal cognitive abilities, which are necessarily improved or the decline prevented by the administration of compositions comprising AA.

Kiliaan et al. does not disclose that LCPUFAs can be administered as constituents of a triglyceride.

JP'891 discloses a method of making triglycerides that contain a high concentration of higher unsaturated fatty acids (LCPUFAs; paragraph [0001]). Positions 1 and 3 of the triglyceride are occupied by medium chain fatty acids, and the higher unsaturated fatty acid is at the 2 position, in a high concentration (paragraph [0009]). Examples of medium chains fatty acids contain 6 – 12 carbon atoms, such as caprylic (8 carbons) or capric acid (10 carbons; paragraph [0011]). With a docosahexanoic acid at the 2 position, a reaction with an 8 carbon medium chain fatty acids resulted in a concentration of the LCPUFA of about 30% (paragraph [0027]). The higher unsaturated fatty acid can be arachidonic acid, docosa-hexaenoic and/or eicosapentaenoic acid (paragraph [0011]). Preparation of these triglycerides allows for a higher concentration of the higher unsaturated fatty acids, which possess various bioactivities (paragraph [0037]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare an AA supplemented formula, with negligible amounts of EPA, to improve cognitive abilities as taught by Wilatts et al. and Barclay, and to prepare a triglyceride as taught by JP'891 in which the LCPUFA is present at the 2 position with medium chain fatty acids at the 1 and 3 positions, given the increased concentrations of the LCPUFA that can be obtained using such a preparation. The amount of triglyceride present in the composition in mole percent is not disclosed. However, amounts of LCPUFA which show effectiveness are presented. An artisan of

ordinary skill in the art would determine the amount of AA that should be administered, and based on the amount of AA present in the prepared triglyceride, and optimize the amount of the triglyceride present in the composition to provide an effective amount of AA. The amount of AA in the composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW